Remarks/Arguments:

I. Status of the Application and Claims

The specification has been amended to include additional information pertaining to related applications and to correct a typographical error. The abstract has also been amended for clarification and to correct a typographical error.

As noted by the Examiner in the Office Action, this application is a national stage entry of International application PCT/US2004/030724. Claims 1 and 20 of the International application were amended under PCT Article 19 during the International stage. These amendments were made in English and communicated by the International Bureau to the USPTO prior to the date of commencement of the national stage. Thus, in accordance with Section 1893.01(a)(2) of the MPEP, such amendments should have been entered by the USPTO. Applicants therefore assume that the claims as amended during the International stage were the claims actually examined by the USPTO in the Office Action mailed December 1, 2009.

Claim 4 is cancelled. Claims 1-3, 5-17, and 19 are amended herein. New claim 47 has been added. Claims 18 and 20-46 are withdrawn from consideration. As a result, claims 1-3, 5-17, 19 and 47 remain pending and under examination.

Support for new claim 47 as well as the amendment to claim 1 is found in Paragraphs [0008] and [0011] of the specification as originally filed. Claims 2, 3, 5-17 and 19 have been amended for the purpose of further clarifying the subject matter being claimed. Claims 9, 12-16 and 19 have also been amended to remove the multiple dependencies. Claim 17 has been amended to correct a typographical error (support for this amendment is found in the first line of Paragraph [0024] of the specification as originally filed). No new matter has been added.

II. Election/Restrictions

Applicants acknowledge that the Examiner has made the previously applied restriction and election of species requirements final, with the exception of the election of species requirement for particle shape which has now been withdrawn.

III. Claim Objections

Claims 9 and 12-16 were objected to under 37 CFR §1.75(c) as being in improper form. Claims 10, 11, 17 and 19 were objected to as being claims which depended from improper multiple dependent claims. These objections have been obviated by amending these claims to remove the multiple dependencies.

IV. Claim Rejections - 35 U.S.C. §112, Second Paragraph

The rejection of claims 4, 5, 7 and 8 under 35 U.S.C. §112, second paragraph, as being indefinite due to the recitation of the term "substantially" has been obviated by cancellation of claim 4 and amendment of the other claims to delete such term. The rejection should therefore be withdrawn.

V. Claim Rejections - 35 U.S.C. §102

A. Rejection of Claims 1 and 2 based on Redkar et al. (US 6,482,830)

Applicants traverse the rejection of claims 1 and 2 under 35 U.S.C. §102(b) as being anticipated by Redkar et al. (US 6,482,830; hereinafter "the Redkar reference"). Reconsideration and withdrawal of the rejection are respectfully requested in view of the claim amendments and arguments presented herein.

Before addressing the Redkar reference in detail, Applicants believe it will be helpful to summarize their invention as reflected in the currently pending claims. The invention is directed to particles for drug delivery by inhalation. These particles comprise both carrier particles (e.g., lactose particles) and particles containing at least one active ingredient which is non-crystalline. The carrier particles are bigger than the particles containing at least one active ingredient. Additionally, the particles containing at least one active ingredient have outer surfaces which are sufficiently smooth so as to minimize forces of adherence between the carrier particles and the particles containing at least one active ingredient. As explained in Paragraph [0011] of Applicants' specification, interlocking between the carrier particles and the active ingredient-containing particles is substantially obviated. It has been found that when a formulation containing such a particle composition enters the air stream, any agglomeration of the active ingredient-containing particles and the carrier particles will readily break up,

increasing the fine particle fraction of the active. This facilitates the reproducible delivery of a substantially accurate dose of active ingredient(s) in an inhalation device, due to the free flow and non-agglomeration of the particles. That is, once any agglomerates of active ingredient-containing particles and carrier particles enter the air stream of a person through inhalation, they will generally break up readily to give a high fine particle fraction which is carried to the lungs (where administration of the active is desired) and carrier particles which lodge in the throat or buccal cavity (thereby reducing the amount of carrier delivered to the lungs).

The Redkar reference is concerned with compositions and formulations of 9-nitrocamptothecin polymorphs. As noted by the Examiner, the reference does disclose a pharmaceutical composition for inhalation comprising an amorphous active agent and a pharmaceutical carrier. However, the Redkar reference does not teach or suggest a composition containing both carrier particles and active ingredient-containing particles, wherein the carrier particles are bigger than the active ingredient-containing particles and the active ingredient-containing particles have surfaces which are sufficiently smooth so as to minimize forces of adherence between the two types of particles. The subject matter of Applicants' claims 1 and 2 thus is not anticipated by the Redkar reference, since the reference fails to disclose each and every element of the claimed invention.

B. Rejection of Claims 1-16 and 19 based on Woolfe et al. (US 2002/0081266)

Applicants traverse the rejection of claims 1-16 and 19 under 35 U.S.C. §102(b) as being anticipated by Woolfe et al. (US 2002/0081266; hereinafter "the Woolfe reference"). Reconsideration and withdrawal of the rejection are respectfully requested in view of the claim amendments and arguments presented herein.

The Woolfe reference concerns formulations for pulmonary or nasal administration comprising a mixture of particles of two or more drugs or excipients produced by spray drying and suitable for administration without further processing of the particles. However, the reference fails to disclose certain features or aspects of Applicants' invention as claimed in the present application. In particular, the Woolfe reference does not teach or suggest a composition containing <u>both</u> carrier particles and active ingredient-containing particles, wherein the carrier particles are bigger than the active ingredient-containing particles and the active ingredient-containing particles contain at least one non-crystalline active ingredient and have surfaces which are sufficiently smooth so as to minimize forces of adherence between the two types of

types of particles. That is, there is no teaching or suggestion in the reference to combine relatively large carrier particles with relatively small active ingredient-containing particles having smooth surfaces to provide a composition suitable for administration by inhalation, whereby any agglomerates of the different particles readily dissociate upon introduction to an airstream due to substantial obviation of particle interlocking. Applicants' claims thus are not anticipated by the Woolfe reference.

VI. Claim Rejections - 35 U.S.C. §103

A. Rejection of Claims 1, 15 and 17 Based on the Woolfe Reference and Keller et al. (US 6,475,467)

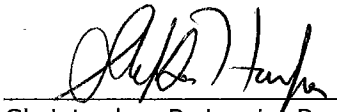
Applicants traverse the rejection of claims 1, 15 and 17 under 35 U.S.C. 103(a) as being unpatentable over the Woolfe reference in view of Keller et al. (US 6,475,467; hereinafter "the Keller reference"). Reconsideration and withdrawal of the rejection are respectfully requested in view of the claim amendments and arguments presented herein.

The Woolfe reference has been previously discussed in connection with the Section 102 rejections. As already noted, the reference is deficient in that it does not disclose a mixture of carrier particles and active ingredient-containing particles, wherein the carrier particles are bigger than the active ingredient-containing particles and the active ingredient-containing particles contain at least one non-crystalline active ingredient and have surfaces which are sufficiently smooth so as to minimize forces of adherence between the two types of particles. These deficiencies are not remedied by the Keller reference. This reference is concerned with medicinal suspension aerosol formulations and to a use of cromoglycic acid and nedocromil salts. In particular, the reference teaches the use of salts of cromoglycic acid and nedocromil as carriers in aerosol formulations, preferably in the form of particles having a mean diameter of less than 6 microns (see Column 6, Lines 16-21). The carrier particle size thus is approximately the same as that of the active compound particles (see Column 6, Lines 9-15). The reference is silent with respect to the crystalline state of the active compound in the active compound particles as well as the surface characteristics of such particles. Thus, an ordinarily skilled person would not have found it obvious from the Keller reference to modify the disclosure of the Woolfe reference to arrive at the invention claimed by Applicants.

VII. Conclusion

The application is believed to be in condition for allowance and early and favorable action is respectfully requested. In the event any issues remain, the Examiner is invited to contact Applicants' legal representatives at the telephone number listed below.

Respectfully submitted,



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Attachments: Abstract

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